


Section I (Amendments to the Claims)

1. (Withdrawn) A method of disinfecting article(s) that are susceptible to contamination by infectious prion protein, the method comprising the steps of:
 - (a) heating said article(s) to a sufficient temperature and for sufficient time to enhance the proteolytic susceptibility of infective prion protein associated with said article(s); and
 - (b) exposing the heated article(s) to a proteolytic enzyme that is effective for at least partial reduction of the infective protein prion associated with said article(s).
2. (Withdrawn) The method of claim 1, wherein said articles comprise surgical instruments.
3. (Withdrawn) The method of claim 2, wherein said surgical instrument(s) are selected from the group consisting of: clamps, forceps, scissors, knives, cables, punches, tweezers, cannulae, calipers, carvers, curettes, scalers, dilators, clip applicators, retractors, contractors, excavators, needle holders, suction tubes, trocars, coagulation electrodes, electroencephalographic depth electrodes, rib and sternum spreaders, bipolar probes, and rib shears.
4. (Withdrawn) The method of claim 1, wherein said article(s) comprise cutleries and kitchen utensils.
5. (Withdrawn) The method of claim 4, wherein said cutleries and kitchen utensils are selected from the group consisting of: knives, forks, scissors, peelers, parers, slicers, spatulas, and cleavers.

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6. (Withdrawn) The method of claim 1, wherein said article(s) comprise laboratory apparatus(es).
 7. (Withdrawn) The method of claim 6, wherein said laboratory apparatus(es) are selected from the group consisting of: containers, filtration devices, centrifuges, spectrophotometers, and fluorometers.
 8. (Withdrawn) The method of claim 1, wherein said article(s) comprise veterinary devices.
 9. (Withdrawn) The method of claim 8, wherein said veterinary devices are selected from the group consisting of clamps, forceps, knives, saws, probes, and electronic stun equipment.
 10. (Withdrawn) The method of claim 1, wherein the temperature in step (a) comprises a temperature not exceeding about 150°C.
 11. (Withdrawn) The method of claim 1, wherein the temperature in step (a) comprises a temperature of at least 35°C.
 12. (Withdrawn) The method of claim 1, wherein the temperature in step (a) comprises a temperature below about 150°C.
 13. (Withdrawn) The method of claim 1, wherein the temperature in step (a) comprises a temperature in a range of from about 100°C to about 150°C.
 14. (Withdrawn) The method of claim 1, wherein the temperature in step (a) comprises a temperature in a range of from about 125°C to about 140°C.
 15. (Withdrawn) The method of claim 1, wherein step (b) is conducted at lower temperature than step (a).

16. (Withdrawn) The method of claim 1, wherein step (b) is carried out at temperature above about 40°C.
17. (Withdrawn) The method of claim 1, wherein step (b) is carried out at temperature above about 50°C.
18. (Withdrawn) The method of claim 1, wherein step (b) is carried out at temperature in a range of from about 35°C to about 75°C.
19. (Withdrawn) The method of claim 1, wherein step (b) is carried out at temperature in a range of from about 40°C to about 75°C.
20. (Withdrawn) The method of claim 1, wherein step (b) is carried out at temperature in a range of from about 50°C to about 65°C.
21. (Withdrawn) The method of claim 1, wherein the proteolytic enzyme comprises at least one enzyme selected from the group consisting of keratinase enzymes, proteinase K, trypsins, chymotrypsins, pepsins, chymosins, cathepsins, subtilisins, elastases, collagenases, endopeptidases, peptidases, oligopeptidase, thermolysins, bacillolysin, mycylisins, carboxypeptidases, leucyl aminopeptidases, aminopeptidases, extremthermophilic proteases, carbonyl hydrolase, papain, pancreatin, streptokinase, streptodornase, ficin, carboxypeptidase, chymopapain, and bromelin.
22. (Withdrawn) The method of claim 1, wherein the proteolytic enzyme comprises a keratinase enzyme.
23. (Withdrawn) The method of claim 1, wherein the proteolytic enzyme comprises an active fragment of a keratinase enzyme.

24. (Withdrawn) The method of claim 1, wherein the proteolytic enzyme comprises a *Bacillus licheniformis* PWD-1 enzyme or an active fragment thereof.
25. (Withdrawn) The method of claim 1, wherein the proteolytic enzyme comprises a protease enzyme.
26. (Withdrawn) The method of claim 25, wherein the protease enzyme comprises a carbonyl hydrolase.
27. (Withdrawn) The method of claim 26, wherein the carbonyl hydrolase comprises subtilisin.
28. (Withdrawn) The method of claim 27, wherein the subtilisin comprises a mutant of wild-type *Bacillus amyloliquefaciens* subtilisin, comprising one or more amino acid substitutions, additions, or deletions.
29. (Withdrawn) The method of claim 25, wherein the protease enzyme comprises at least one enzyme selected from the group consisting of: papain, pancreatin, trypsin, chymotrypsin, pepsin, streptokinase, streptodornase, ficin, carboxypeptidase, aminopeptidase, chymopapain, bromelin, and subtilisin.
30. (Withdrawn) A method of removing infective prion protein from a surgical instrument contaminated with same, the method including (a) heating the surgical instrument at a temperature in a range of from about 100°C to about 150°C, followed by (b) exposing the heated surgical instrument to a proteolytic enzyme at a temperature in a range of from about 35°C to about 100°C at which the proteolytic enzyme is thermally stable and proteolytically effective to at least partially destroy the infective prion protein contaminating said surgical instrument.

31. (Withdrawn) The method of claim 30, wherein said heating is conducted for a time of from about 5 minutes to about 5 hours.
32. (Withdrawn) The method of claim 30, wherein the proteolytic enzyme comprises at least one enzyme selected from the group consisting of keratinase enzymes, proteinase K, trypsins, chymotrypsins, pepsins, chymosins, cathepsins, subtilisins, elastases, collagenases, endopeptidases, peptidases, oligopeptidase, thermolysins, bacillolysin, mycilysins, carboxypeptidases, leucyl aminopeptidases, aminopeptidases, extremthermophilic proteases, carbonyl hydrolase, papain, pancreatin, streptokinase, streptodornase, ficin, carboxypeptidase, chymopapain, and bromelin.
33. (Withdrawn) The method of claim 30, wherein the proteolytic enzyme comprises *Bacillus licheniformis* PWD-1 keratinase.
34. (Withdrawn) The method of claim 1, wherein the proteolytic enzyme comprises a protease enzyme.
35. (Withdrawn) The method of claim 34, wherein the protease enzyme comprises a carbonyl hydrolase.
36. (Withdrawn) The method of claim 35, wherein the carbonyl hydrolase comprises subtilisin.
37. (Withdrawn) The method of claim 36, wherein the subtilisin comprises a mutant of wild-type *Bacillus amyloliquefaciens* subtilisin, comprising one or more amino acid substitutions, additions, or deletions.
38. (Withdrawn) The method of claim 34, wherein the protease enzyme comprises at least one enzyme selected from the group consisting of: papain, pancreatin, trypsin,

chymotrypsin, pepsin, streptokinase, streptodornase, ficin, carboxypeptidase, aminopeptidase, chymopapain, bromelin, and subtilisin.

39. (Currently amended) A ~~cleansing composition~~ system for disinfecting articles that are susceptible to contamination by infectious prion protein, said ~~composition~~ system comprising:

(a) said articles;

(b) means for heating said articles to a sufficient temperature and for sufficient time to enhance the proteolytic susceptibility of infectious prion protein associated with said article(s);

(c) a proteolytic enzyme that is effective for at least partial reduction of the infectious prion protein associated with said articles; and

(d) means for exposing said articles to said proteolytic enzyme

~~one or more proteolytic protein(s) selected from the group consisting of keratinase enzymes, proteinase K, trypsins, chymotrypsins, pepsins, chymosins, cathepsins, subtilisins, elastases, collagenases, endopeptidases, peptidases, oligopeptidase, thermolysins, bacillolysin, mycilysins, carboxypeptidases, leucyl aminopeptidases, aminopeptidases, extremothermophilic proteases, carbonyl hydrolase, papain, pancreatin, streptokinase, streptodornase, ficin, carboxypeptidase, chymopapain, and bromelin; and a solvent.~~

40. (Currently amended) The ~~cleansing composition~~ system of claim 39, ~~comprising wherein~~ the proteolytic enzyme comprises keratinase ~~enzymes~~.

41. (Currently amended) The ~~cleansing composition~~ system of claim 40, wherein the ~~concentration of said keratinase enzymes~~ is provided in a solution at a concentration with the within a range of from about 0.2 g/L to about 1.0 g/L.
42. (Currently amended) The ~~cleansing composition~~ system of claim 39 ~~41~~, wherein the solution comprises a solvent is selected from the group consisting of distilled water, alcohol, buffer solution, and detergent solution.
43. (Currently amended) The ~~cleansing composition~~ system of claim 39 ~~42~~, wherein said solution further comprising comprises one or more chemical additives selected from the group consisting of surfactants, builders, boosters, and fillers.
44. (New) The system of claim 39, wherein said articles comprise surgical instruments.
45. (New) The system of claim 44, wherein said surgical instrument(s) are selected from the group consisting of: clamps, forceps, scissors, knives, cables, punches, tweezers, cannulae, calipers, carvers, curettes, scalers, dilators, clip applicators, retractors, contractors, excavators, needle holders, suction tubes, trocars, coagulation electrodes, electroencephalographic depth electrodes, rib and sternum spreaders, bipolar probes, and rib shears.
46. (New) The system of claim 39, wherein said articles comprise cutleries and kitchen utensils.
47. (New) The system of claim 46, wherein said cutleries and kitchen utensils are selected from the group consisting of: knives, forks, scissors, peelers, parers, slicers, spatulas, and cleavers.
48. (New) The system of claim 39, wherein said articles comprise laboratory apparatuses.

48. (New) The system of claim 47, wherein said laboratory apparatuses are selected from the group consisting of: containers, filtration devices, centrifuges, spectrophotometers, and fluorometers.
49. (New) The system of claim 39, wherein said article(s) comprise veterinary devices.
50. (New) The system of claim 49, wherein said veterinary devices are selected from the group consisting of clamps, forceps, knives, saws, probes, and electronic stun equipment.
51. (New) The system of claim 39, wherein said heating device heats said articles to a temperature of not exceeding about 150°C.
52. (New) The system of claim 39, wherein said heating device heats said articles to a temperature of at least about 35°C.
53. (New) The system of claim 39, wherein said heating device heats said articles to a temperature of below about 150°C.
54. (New) The system of claim 39, wherein said heating device heats said articles to a temperature in a range of from about 100°C to about 150°C.
55. (New) The system of claim 39, wherein said heating device heats said articles to a temperature in a range of from about 125°C to about 140°C.
56. (New) The system of claim 39, wherein the heated articles are exposed to the proteolytic enzyme at a temperature that is lower than the temperature to which the articles are heated by the heating device.
57. (New) The system of claim 39, wherein the heated articles are exposed to the proteolytic enzyme at a temperature above about 40°C.

58. (New) The system of claim 39, wherein the heated articles are exposed to the proteolytic enzyme at a temperature above about 50°C.
59. (New) The system of claim 39, wherein the heated articles are exposed to the proteolytic enzyme at a temperature in a range of from about 35°C to about 75°C.
60. (New) The system of claim 39, wherein the heated articles are exposed to the proteolytic enzyme at a temperature in a range of from about 40°C to about 75°C.
61. (New) The system of claim 39, wherein the heated articles are exposed to the proteolytic enzyme at a temperature in a range of from about 50°C to about 65°C.
62. (New) The system of claim 39, wherein the proteolytic enzyme comprises at least one enzyme selected from the group consisting of keratinase enzymes, proteinase K, trypsins, chymotrypsins, pepsins, chymosins, cathepsins, subtilisins, elastases, collagenases, endopeptidases, peptidases, oligopeptidase, thermolysins, bacillolysin, mycilysins, carboxypeptidases, leucyl aminopeptidases, aminopeptidases, extremthermophilic proteases, carbonyl hydrolase, papain, pancreatin, streptokinase, streptodornase, ficin, carboxypeptidase, chymopapain, and bromelin.
63. (New) The system of claim 39, wherein the proteolytic enzyme comprises a keratinase enzyme.
64. (New) The system of claim 39, wherein the proteolytic enzyme comprises an active fragment of a keratinase enzyme.
65. (New) The system of claim 39, wherein the proteolytic enzyme comprises a *Bacillus licheniformis* PWD-1 enzyme or an active fragment thereof.

66. (New) The system of claim 39, wherein the proteolytic enzyme comprises a protease enzyme.
67. (New) The system of claim 39, wherein the protease enzyme comprises a carbonyl hydrolase.
68. (New) The system of claim 67, wherein the carbonyl hydrolase comprises subtilisin.
69. (New) The system of claim 68, wherein the subtilisin comprises a mutant of wild-type *Bacillus amyloliquefaciens* subtilisin, comprising one or more amino acid substitutions, additions, or deletions.
70. (New) The system of claim 66, wherein the protease enzyme comprises at least one enzyme selected from the group consisting of: papain, pancreatin, trypsin, chymotrypsin, pepsin, streptokinase, streptodornase, ficin, carboxypeptidase, aminopeptidase, chymopapain, bromelin, and subtilisin.
71. (New) A system for removing infective prion protein from a surgical instrument contaminated with same, the system comprising (a) means for heating the surgical instrument to a temperature in a range of from about 100°C to about 150°C, (b) a proteolytic enzyme that is thermally stable at a temperature in a range of from about 35°C to about 100°C and proteolytically effective to at least partially destroy the infective prion protein contaminating said surgical instrument, and (c) means for exposing the heated surgical instrument to the proteolytic enzyme at a temperature in a range of from about 35°C to about 100°C.
72. (New) The system of claim 71, wherein said surgical instrument is heated by said heating means for a time of from about 5 minutes to about 5 hours.

73. (New) The system of claim 71, wherein the proteolytic enzyme comprises at least one enzyme selected from the group consisting of keratinase enzymes, proteinase K, trypsins, chymotrypsins, pepsins, chymosins, cathepsins, subtilisins, elastases, collagenases, endopeptidases, peptidases, oligopeptidase, thermolysins, bacillolysin, mycilysins, carboxypeptidases, leucyl aminopeptidases, aminopeptidases, extremothermophilic proteases, carbonyl hydrolase, papain, pancreatin, streptokinase, streptodornase, ficin, carboxypeptidase, chymopapain, and bromelin.
74. (New) The system of claim 71, wherein the proteolytic enzyme comprises *Bacillus licheniformis* PWD-1 keratinase.
75. (New) The system of claim 71, wherein the proteolytic enzyme comprises a protease enzyme.
76. (New) The system of claim 75, wherein the protease enzyme comprises a carbonyl hydrolase.
77. (New) The system of claim 76, wherein the carbonyl hydrolase comprises subtilisin.
78. (New) The system of claim 77, wherein the subtilisin comprises a mutant of wild-type *Bacillus amyloliquefaciens* subtilisin, comprising one or more amino acid substitutions, additions, or deletions.
79. (New) The system of claim 75, wherein the protease enzyme comprises at least one enzyme selected from the group consisting of: papain, pancreatin, trypsin, chymotrypsin, pepsin, streptokinase, streptodornase, ficin, carboxypeptidase, aminopeptidase, chymopapain, bromelin, and subtilisin.

80. (New) A system for disinfecting articles that are susceptible to contamination by infectious prion protein, comprising:

- (a) said articles;
- (b) means for heating said articles to a temperature in a range of about 35-150°C for a sufficient period of time to enhance proteolytic susceptibility of said infective prion protein;
- (c) *Bacillus licheniformis* PWD-1 keratinase; and
- (d) means for exposing the heated articles e to the *Bacillus licheniformis* PWD-1 keratinase at a temperature in a range of about 35-100°C for a sufficient period of time.

81. (New) The system of claim 80, further comprising means for verifying disinfection of the articles with respect to prion contamination.

82. (New) A system for disinfecting articles that are susceptible to contamination by infectious prion protein, comprising:

- (a) said articles;
- (b) *Bacillus licheniformis* PWD-1 keratinase; and
- (b) means for exposing the articles to *Bacillus licheniformis* PWD-1 keratinase at a temperature in a range of about 35-100°C for a sufficient period of time to degrade the prion protein.

83. (New) The system of claim 82, further comprising means for verifying disinfection of the articles with respect to prion contamination.